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510(k) Summary of Safety and Effectiveness

1. Sponsor Name

Radius Medical Technologies, Inc.
63 Great Road
Maynard, MA 01754
Telephone: 978 897 6469
Contact Individual: Debbie Iampietro

2. Device Name

Proprietary Name: Next Generation Guidewire
Common/Usual Name: Guidewire
Classification Name: Endoscope and accessory

3. Identification of Predicate or Legally Marketed Device

The Next Generation Guidewire is substantially equivalent to the Microvasive Geenen Endotorque Guidewire (K942677)
Boston Scientific Microvasive Jagwire (510(k) number unknown)

4. Device Description

Radius Medical Technologies, Inc. has developed a line of Endoscopic guidewires ranging in sizes of 0.025" to 0.035" diameter and lengths of 260 cm to 450 cm (in standard and stiff body types). The wires will be offered with a 5 cm radiopaque distal tip (angled and straight). The wires are constructed of a solid nitinol core wire, which tapers at its distal end. A shrink jacket surrounds the core over the entire length except the distal most 5 cm. A radiopaque tube covers the distal 5 cm. Single striped bands of ink are placed circumferentially onto the jacket and spaced in 1 cm intervals beginning at the 6 cm location and continuing to the 40 cm location from the distal tip. Multiple ink bands are used to delineate the 10, 15, and 20 cm locations. A coating is applied over the tip portion of the guidewire.

5. Intended Use

The Next Generation Guidewire is designed to be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures. The guidewire is indicated for selective cannulation of the biliary ducts, including but not limited to the common bile duct, cystic, pancreatic, and right and left hepatic ducts.

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6. Comparison of Technological Characteristics

The Next Generation Guidewire is substantially equivalent to the Boston Scientific Microvasive Jagwire and the Microvasive Geenen Endotorque Guidewire. The Radius Medical Next Generation Guidewire is substantially equivalent to the predicate devices listed, which provide the same or similar functions. The intended use and technological characteristics including, design, materials and method of operation support the concept of substantial equivalence.

7 Performance Testing

Testing on the Next Generation Guidewire includes distal tip tensile, torqueability, tip flexibility, coating adherence/integrity, and electrical resistance (in accordance with AAMI HF 18).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2001

Ms. Maureen A. Finlayson
President
Radius Medical Technologies, Inc.
63 Great Road
MAYNARD MA 01754

Re: K011759
Next Generation Guidewire
Dated: June 1, 2001
Received: June 6, 2001
Regulatory class: II
21 CFR 876.1500/Procode: 78 KOG
21 CFR 876.5010/Procode: 78 GCA

Dear Ms. Finlayson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011759

Device Name: Radius Medical Technologies Next Generation Guidewire

Indications For Use:

The Next Generation Guidewire is designed to be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures. The guidewire is indicated for selective cannulation of the biliary ducts, including but not limited to the common bile duct, cystic, pancreatic, and right and left hepatic ducts.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011759